



US006022319A

United States Patent [19]

[11] **Patent Number:** **6,022,319**

Willard et al.

[45] **Date of Patent:** ***Feb. 8, 2000**

[54] **INTRAVASCULAR DEVICE SUCH AS INTRODUCER SHEATH OR BALLOON CATHETER OR THE LIKE AND METHODS FOR USE THEREOF**

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[*] Notice: Under 35 U.S.C. 154(b), the term of this patent shall be extended for 245 days.

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[21] Appl. No.: **08/498,946**

[22] Filed: **Jul. 5, 1995**

Related U.S. Application Data

[63] Continuation of application No. 08/075,681, Jun. 11, 1993, which is a continuation of application No. 07/809,715, Dec. 18, 1991, Pat. No. 5,219,335, which is a continuation-in-part of application No. 07/704,828, May 23, 1991, abandoned, which is a continuation-in-part of application No. 07/946,000, Sep. 15, 1992, abandoned, which is a continuation of application No. 07/704,828, May 23, 1991, abandoned.

[51] **Int. Cl.**⁷ **A61B 8/12**

[52] **U.S. Cl.** **600/470; 606/194**

[58] **Field of Search** 128/657, 658, 128/662.06, 663.01, 772; 604/22, 160, 161, 164, 264, 280; 606/194

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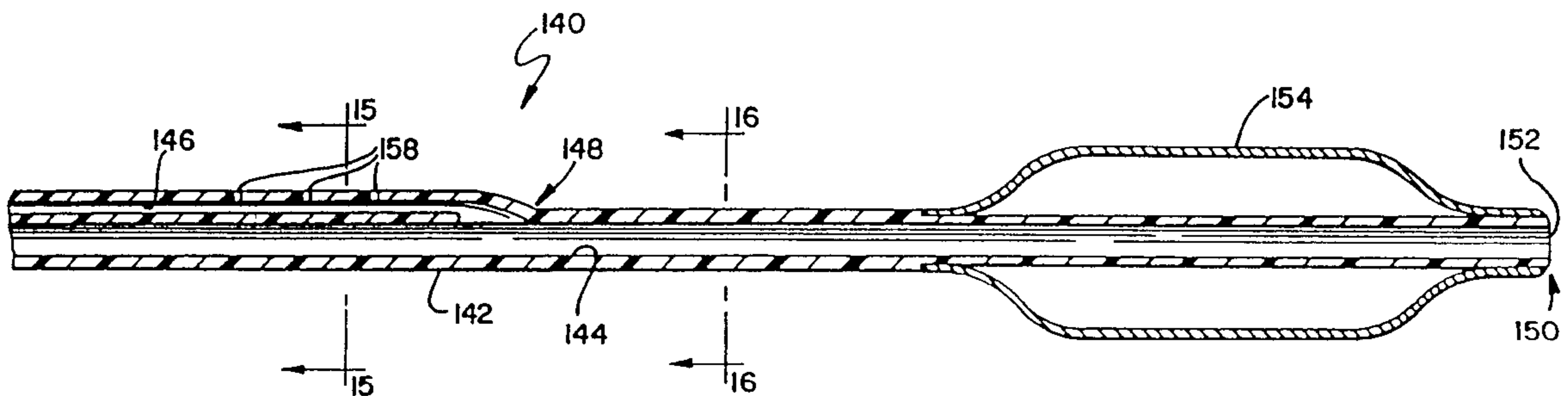
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Attorney, Agent, or Firm—Lyon & Lyon LLP

[57] **ABSTRACT**

An intravascular device such as an introducer sheath or a balloon catheter, and methods for use thereof, comprising an elongate member having a proximal end and a distal end and a first lumen and a second lumen. The first lumen communicates with a first proximal opening at the proximal end of the elongate member and with a distal opening at the distal end of the elongate member. The second lumen terminates distally and communicates with the first lumen at a location proximal of the first distal opening and has a proximal opening located proximally therefrom. One or more perfusion openings may be located in the device to allow blood flow therethrough. The proximal opening of the second lumen may be located distally of the proximal opening of the first lumen. A balloon may be located on a distal portion of the elongate shaft.

7 Claims, 5 Drawing Sheets



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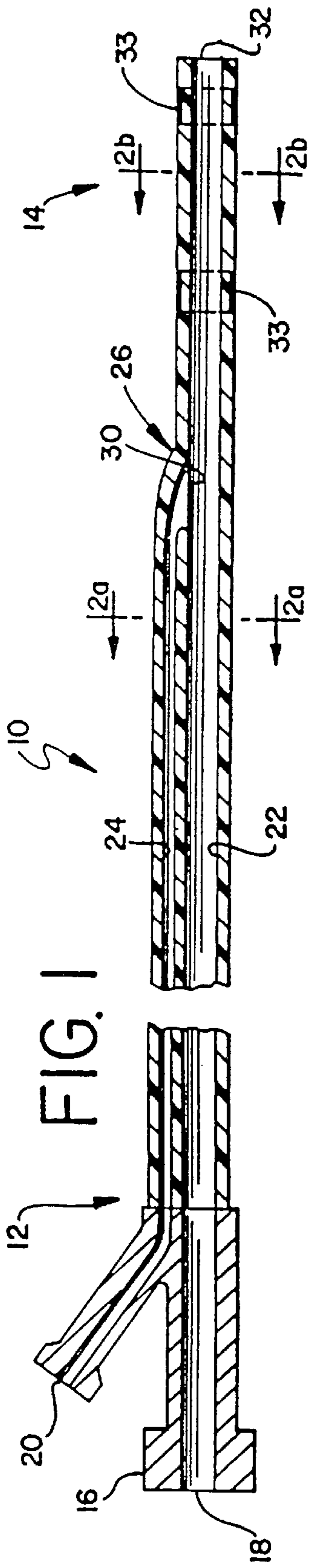


FIG. 1

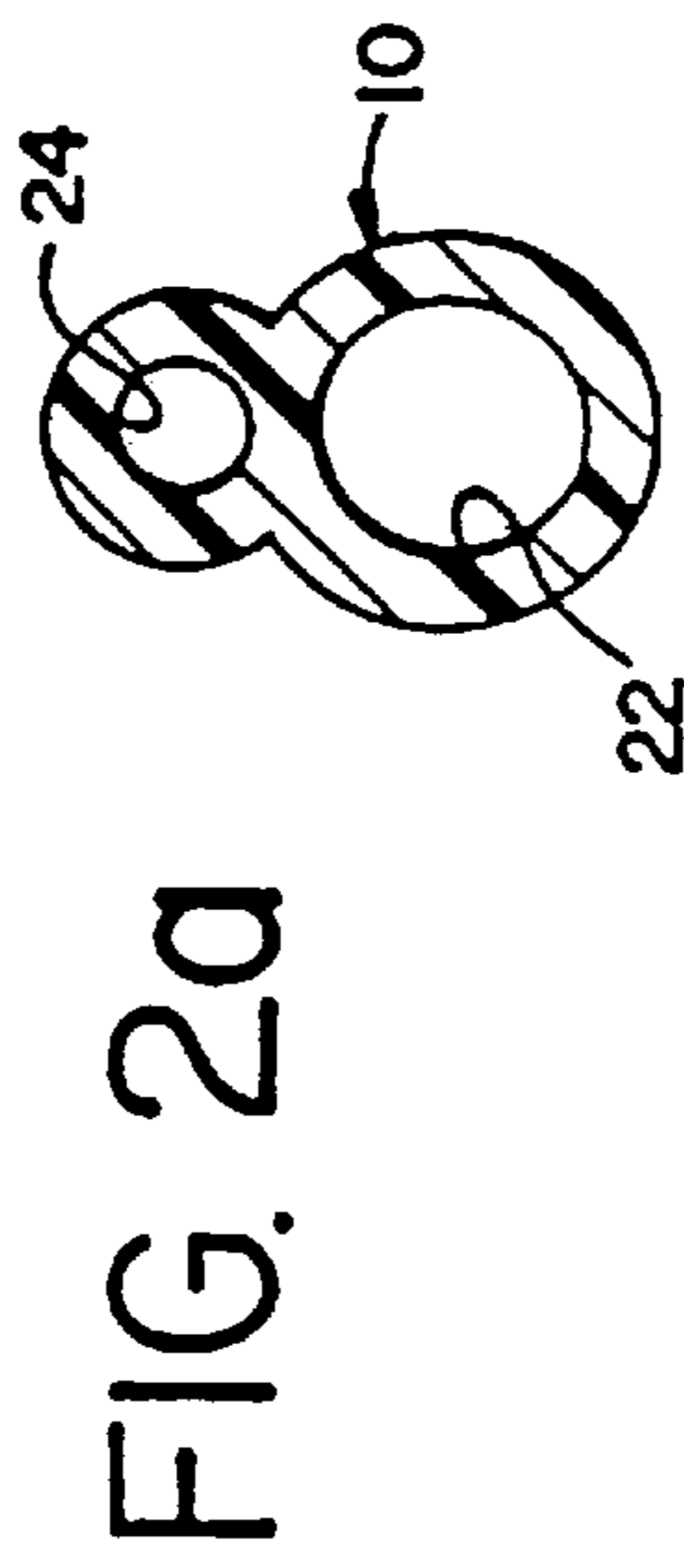


FIG. 2a

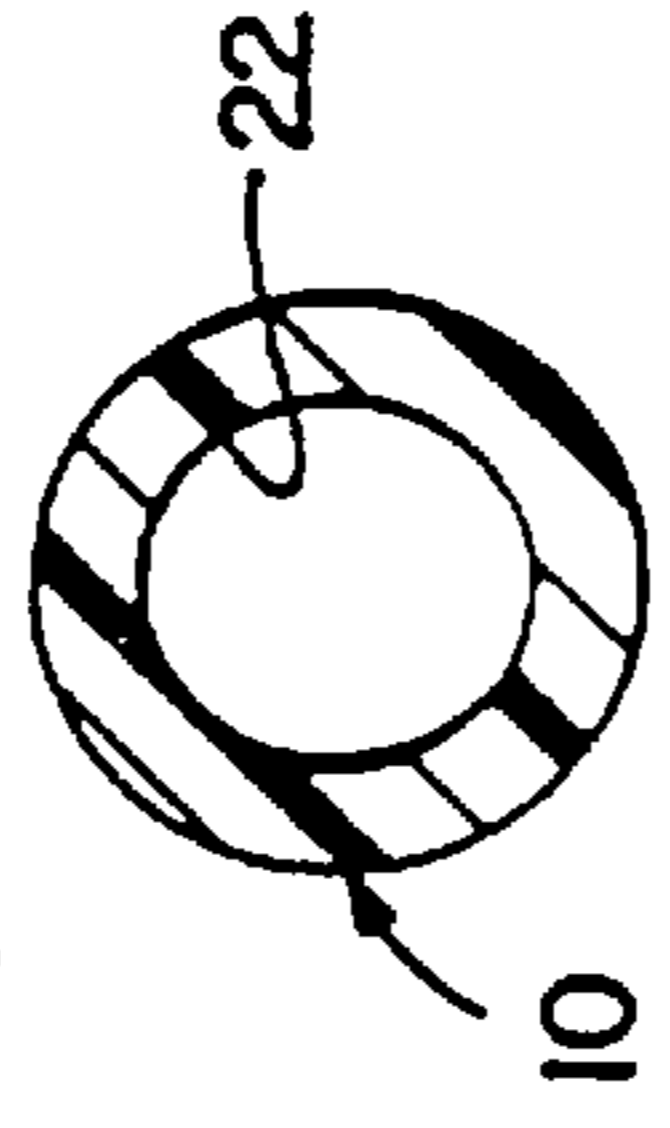


FIG. 2b

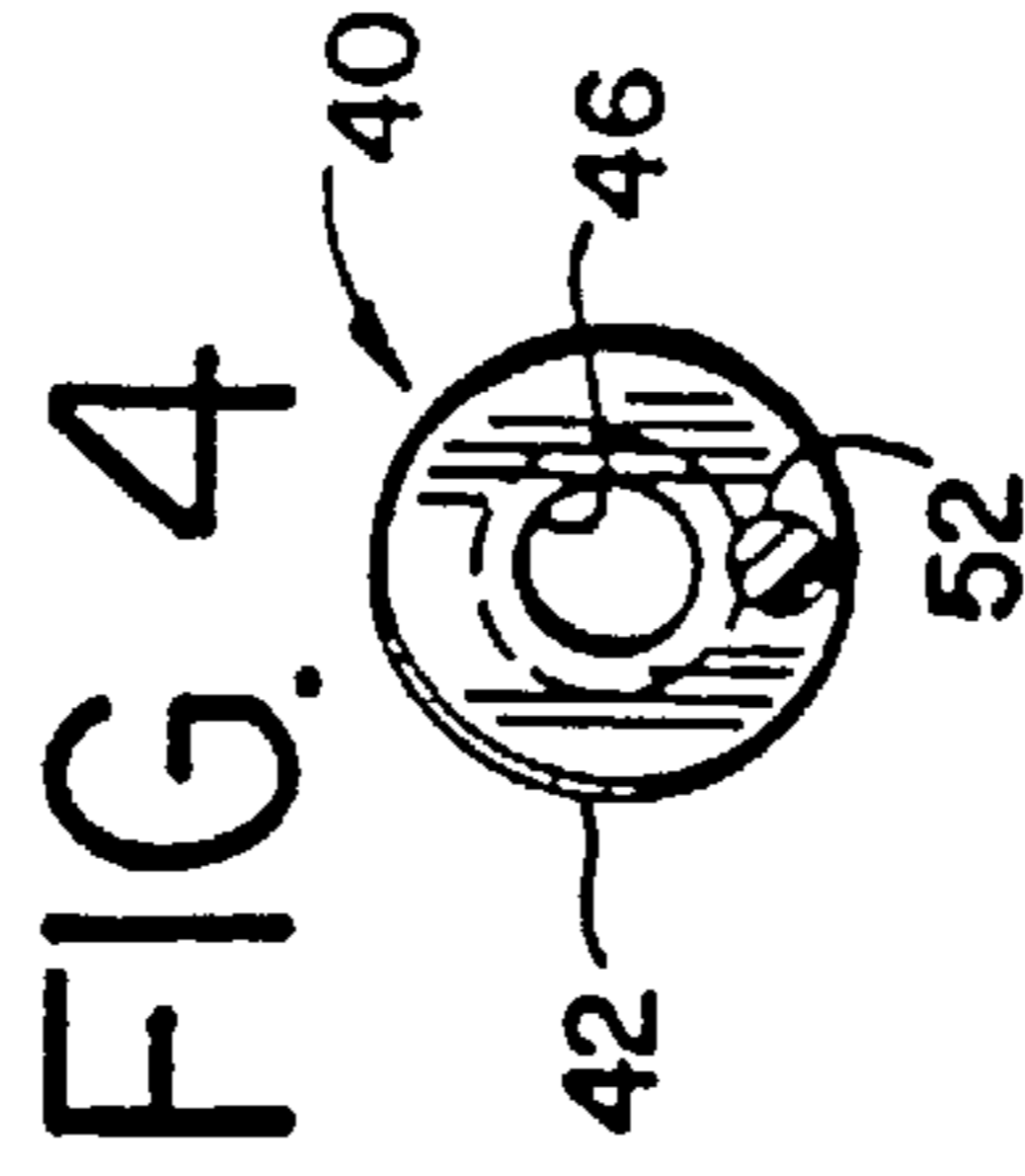


FIG. 4

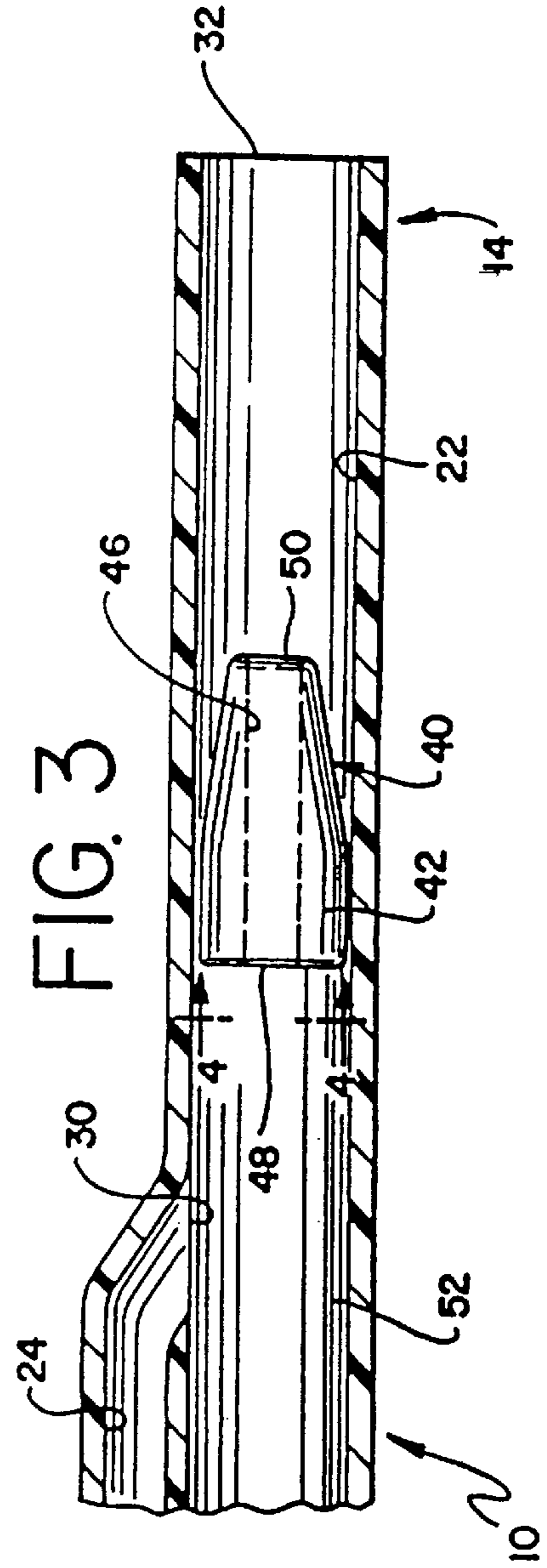


FIG. 3

FIG. 5

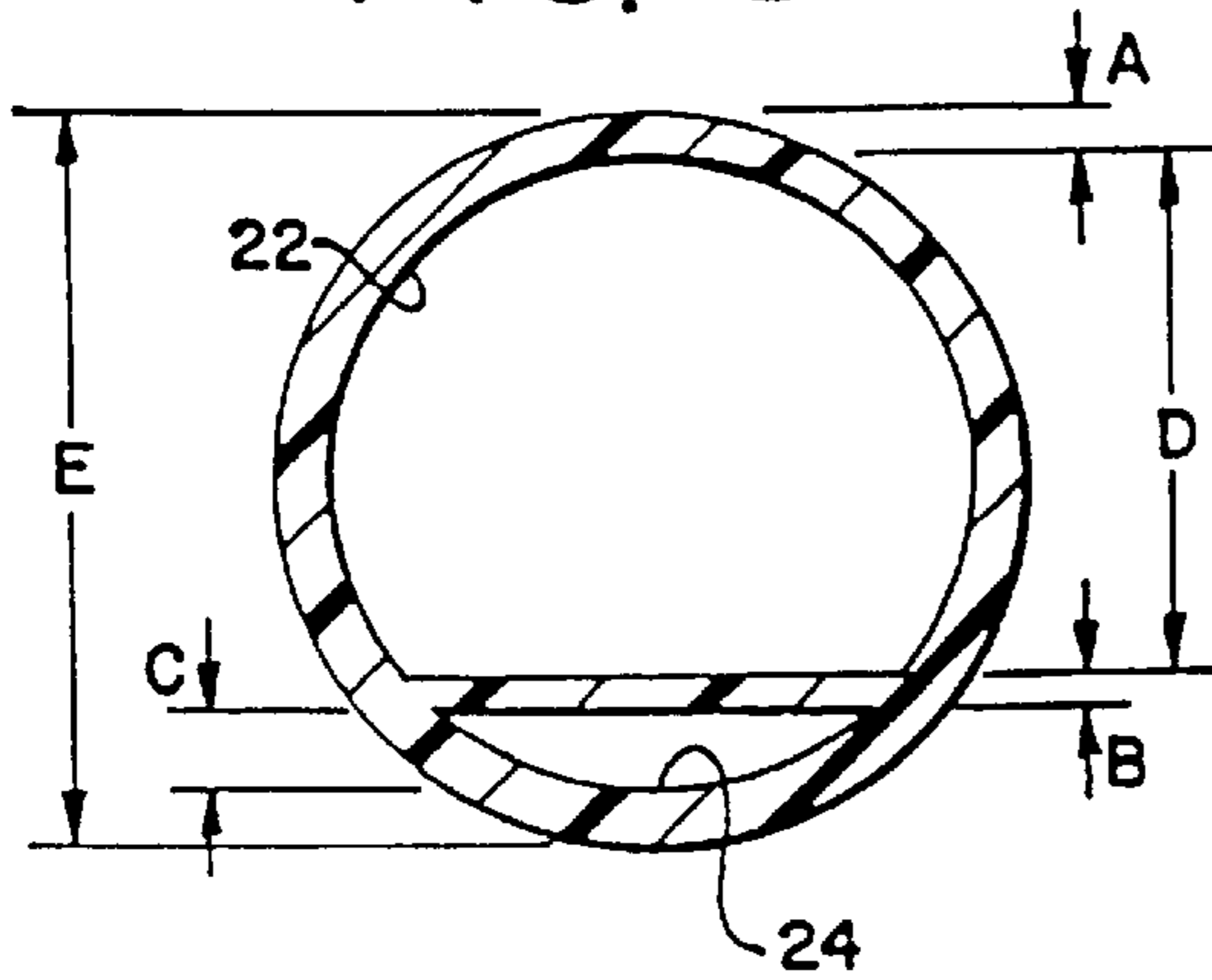


FIG. 6

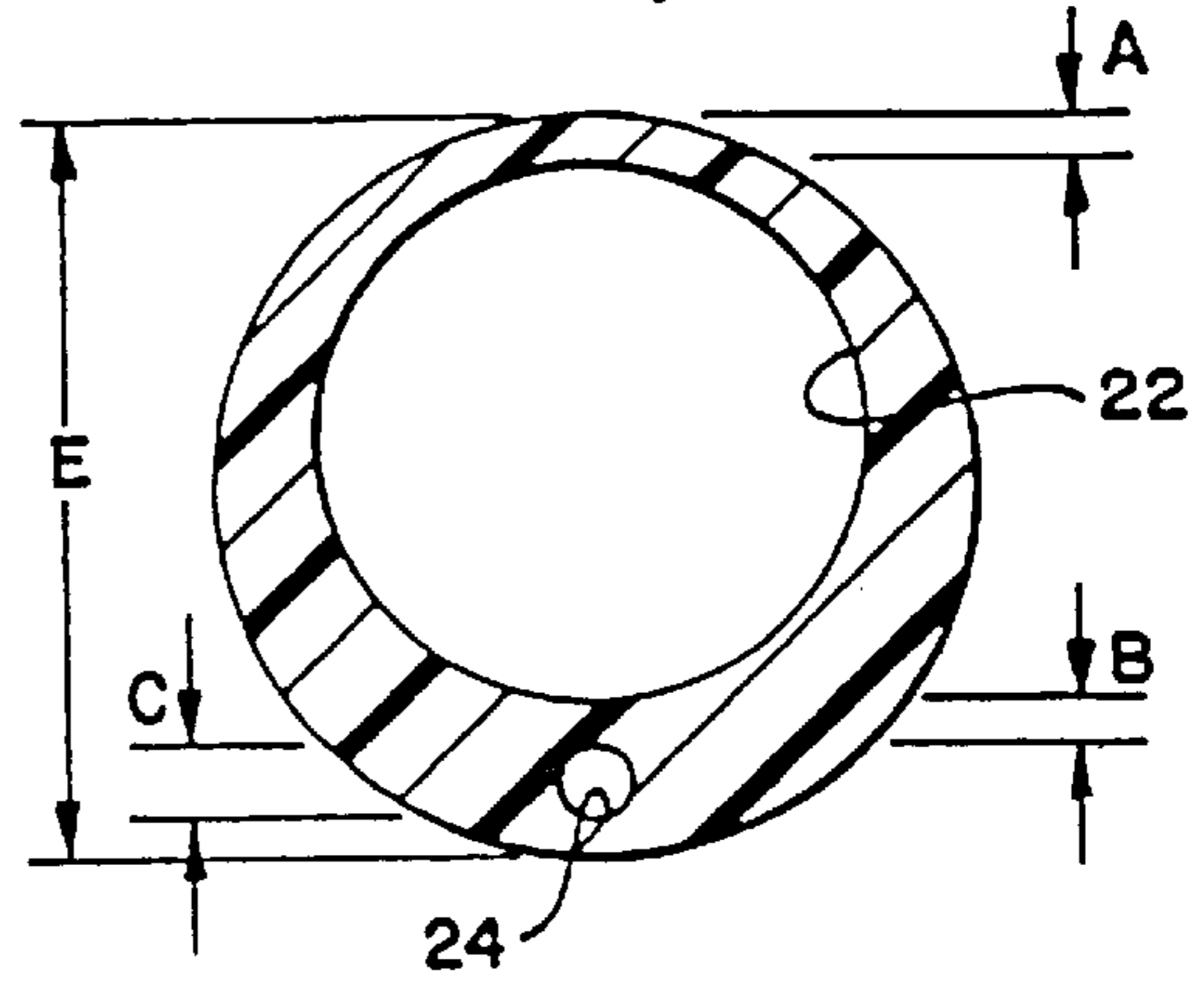


FIG. 7

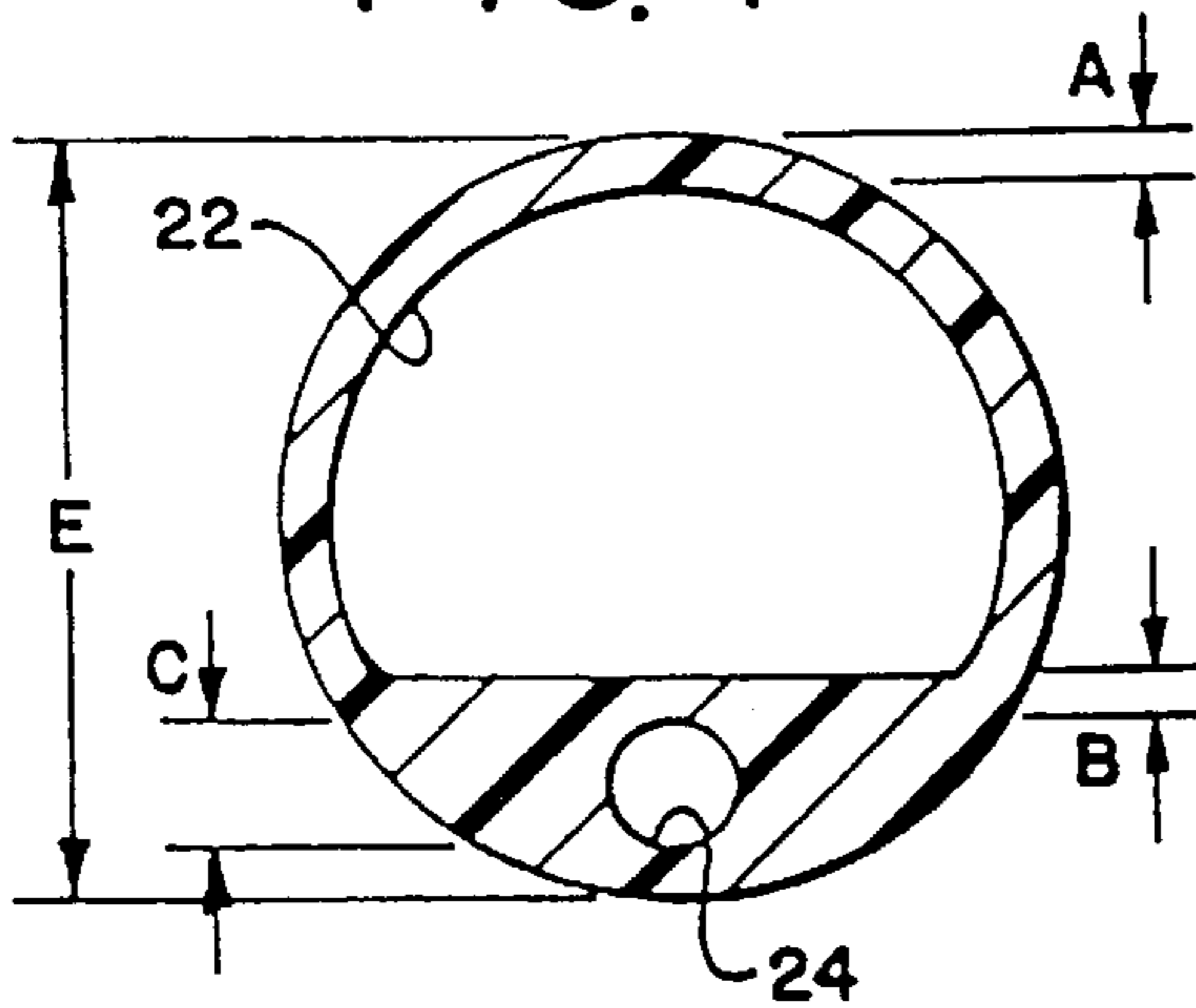


FIG. 8

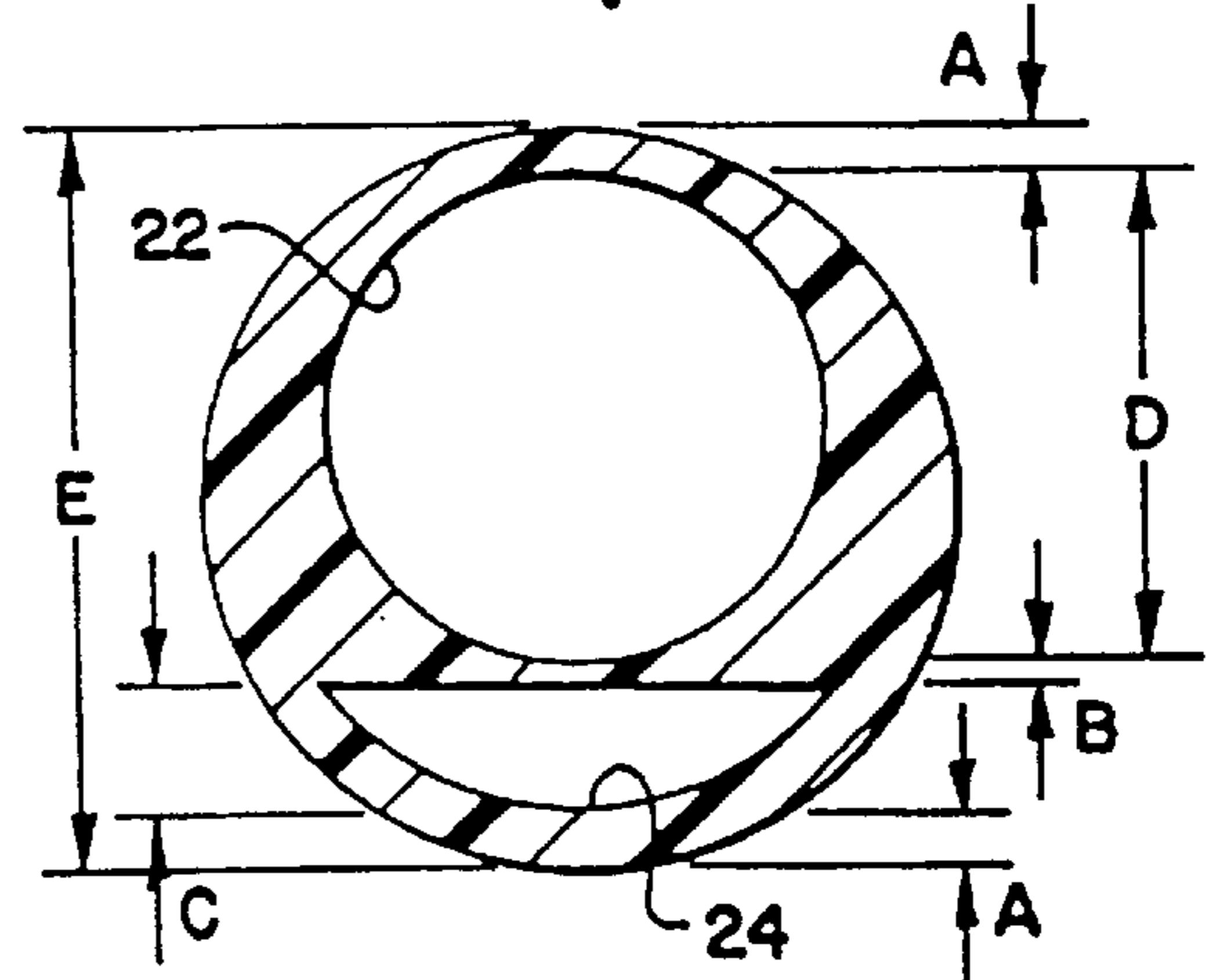
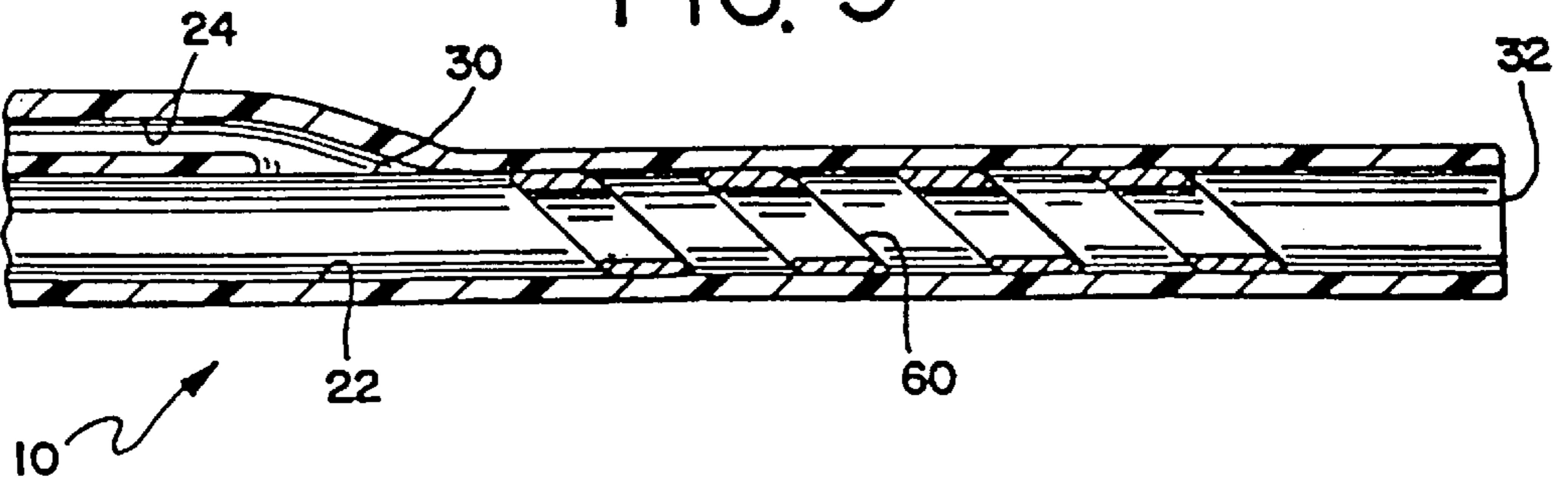


FIG. 9



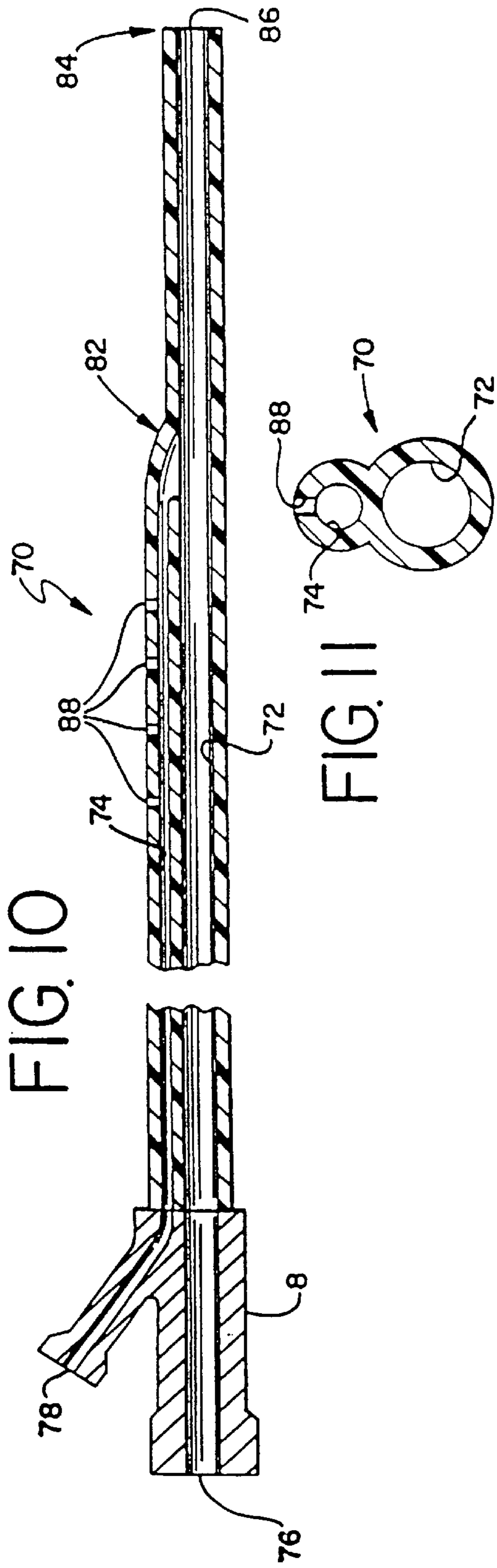


FIG. 11

FIG. 10

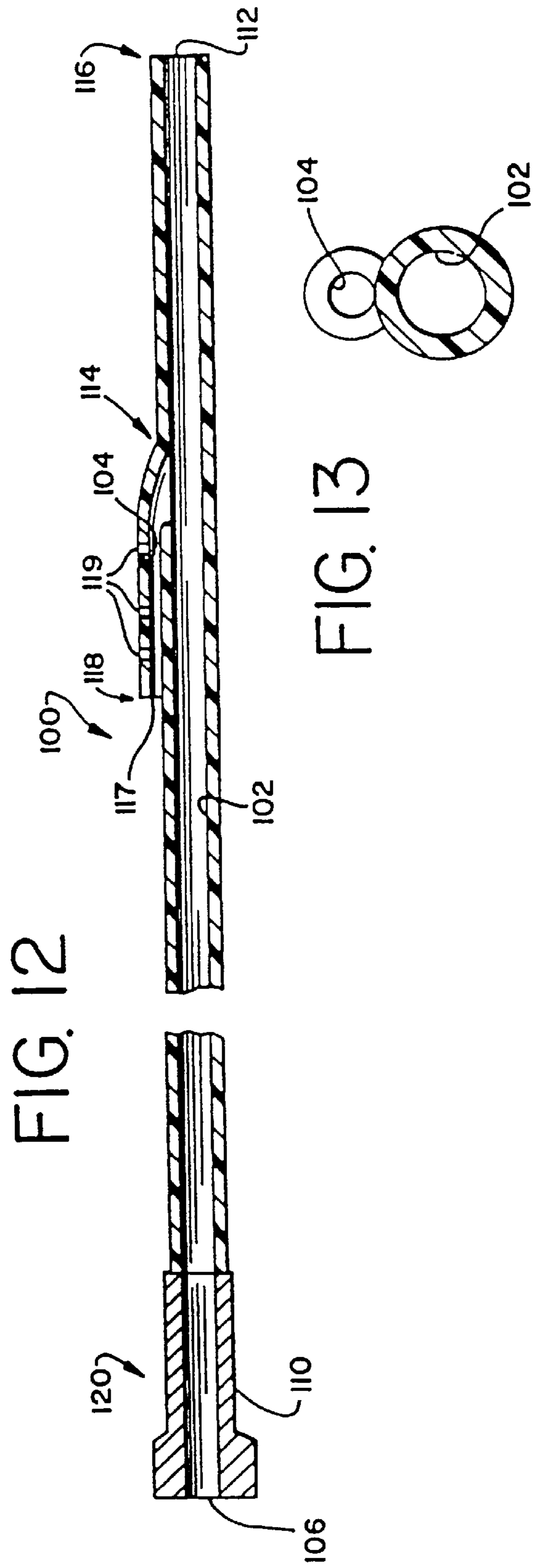


FIG. 12

FIG. 13

FIG. 14

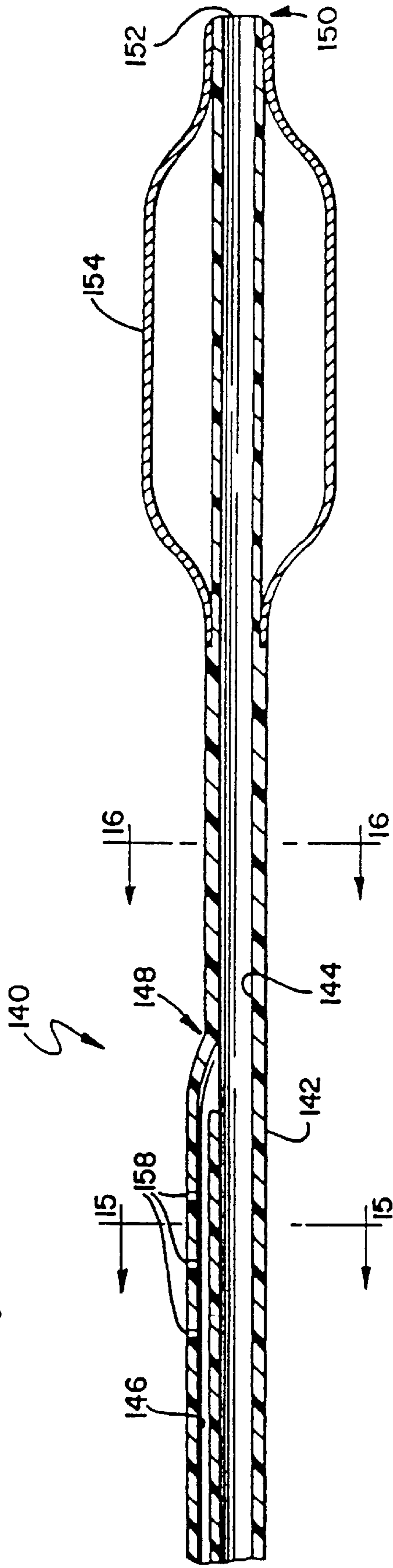


FIG. 15

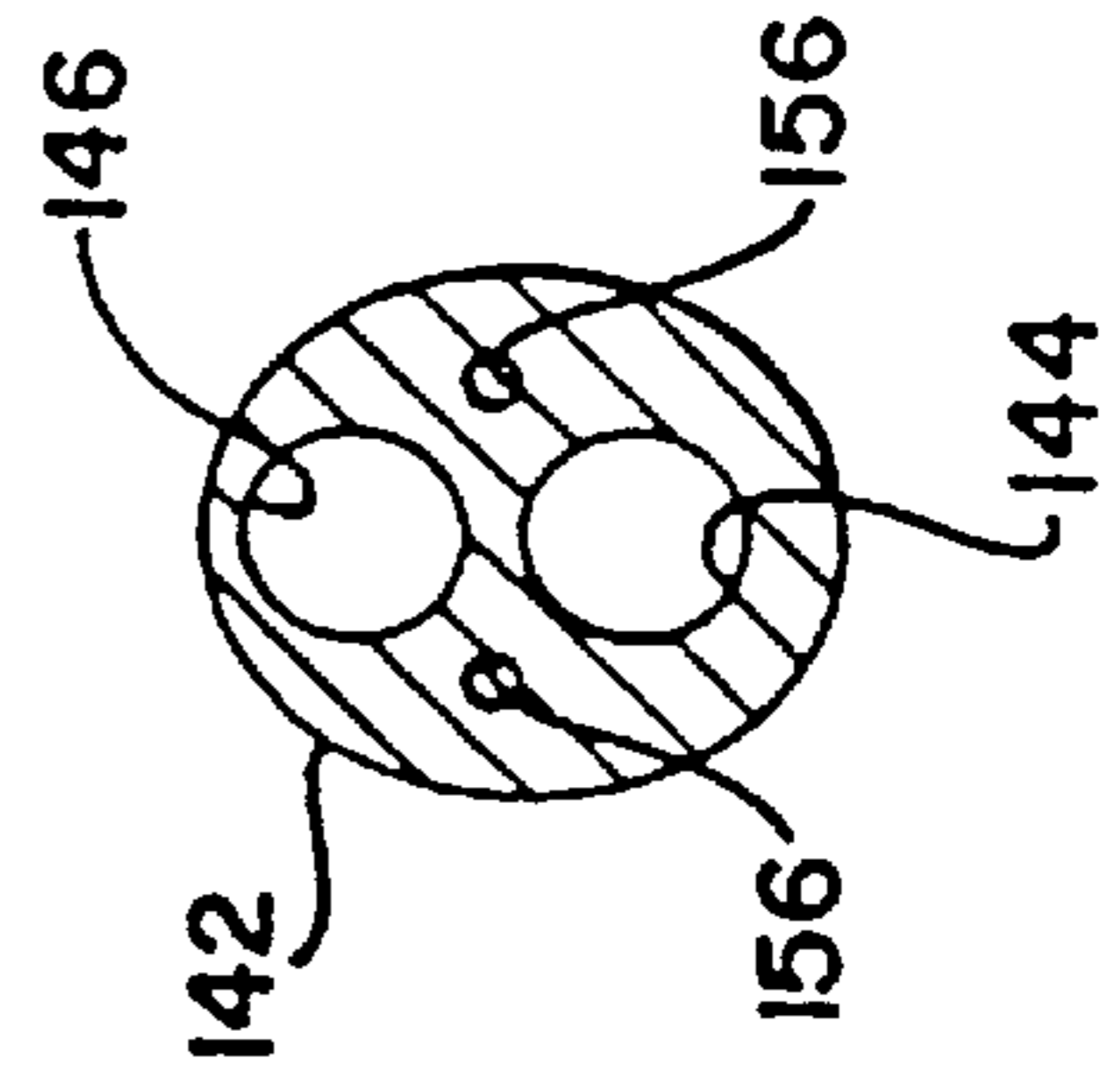


FIG. 16

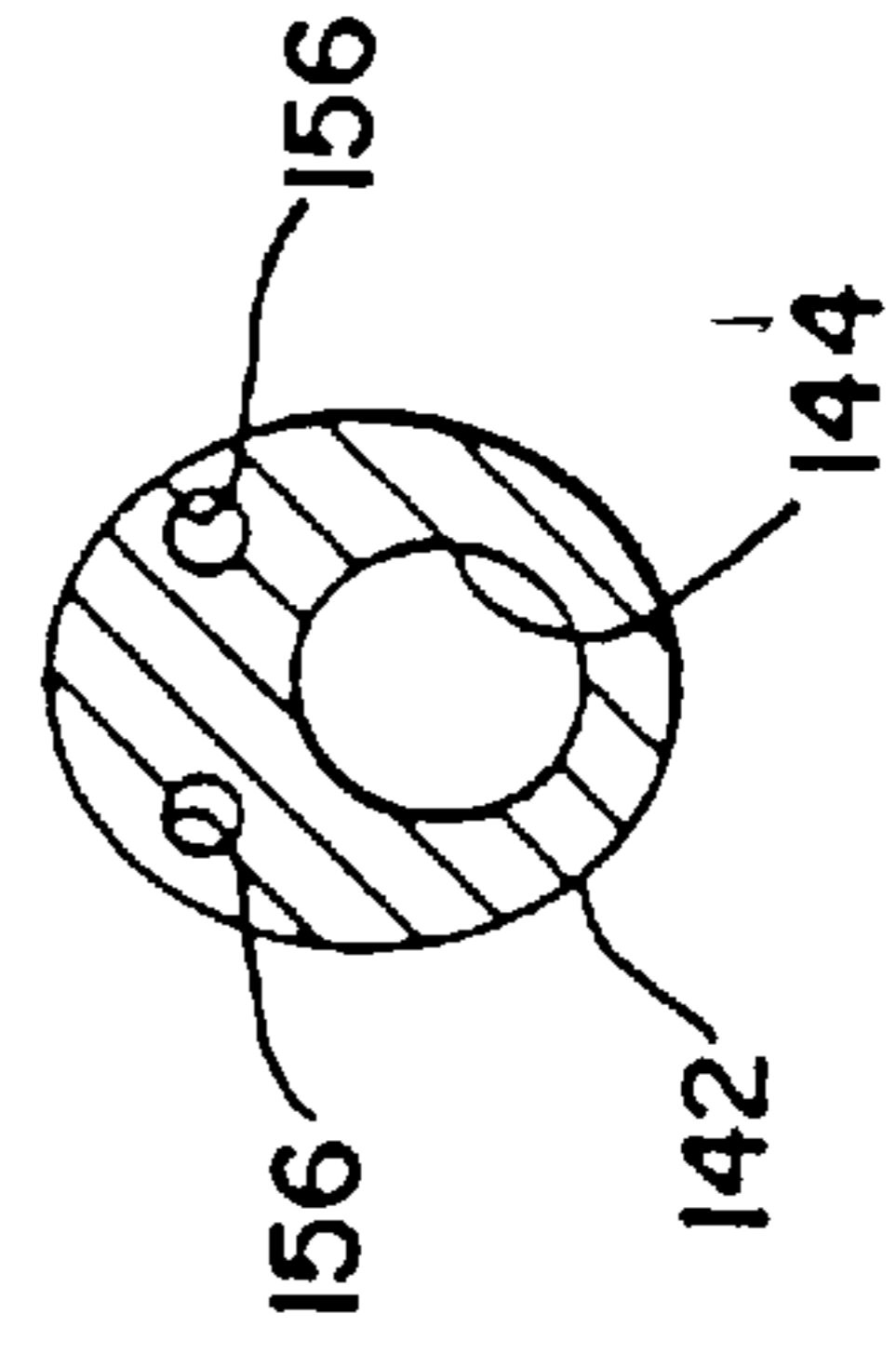


FIG. 17

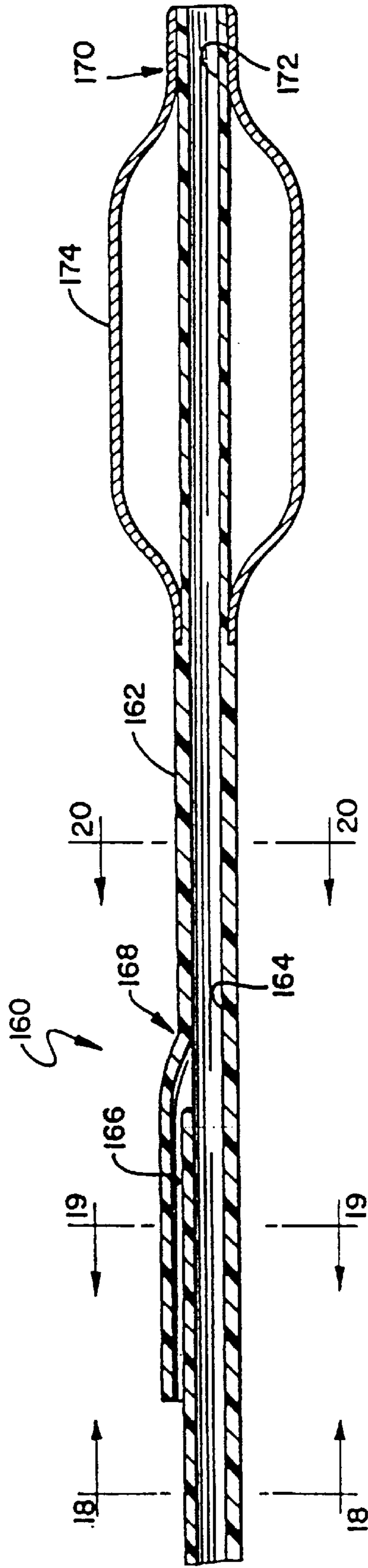


FIG. 18

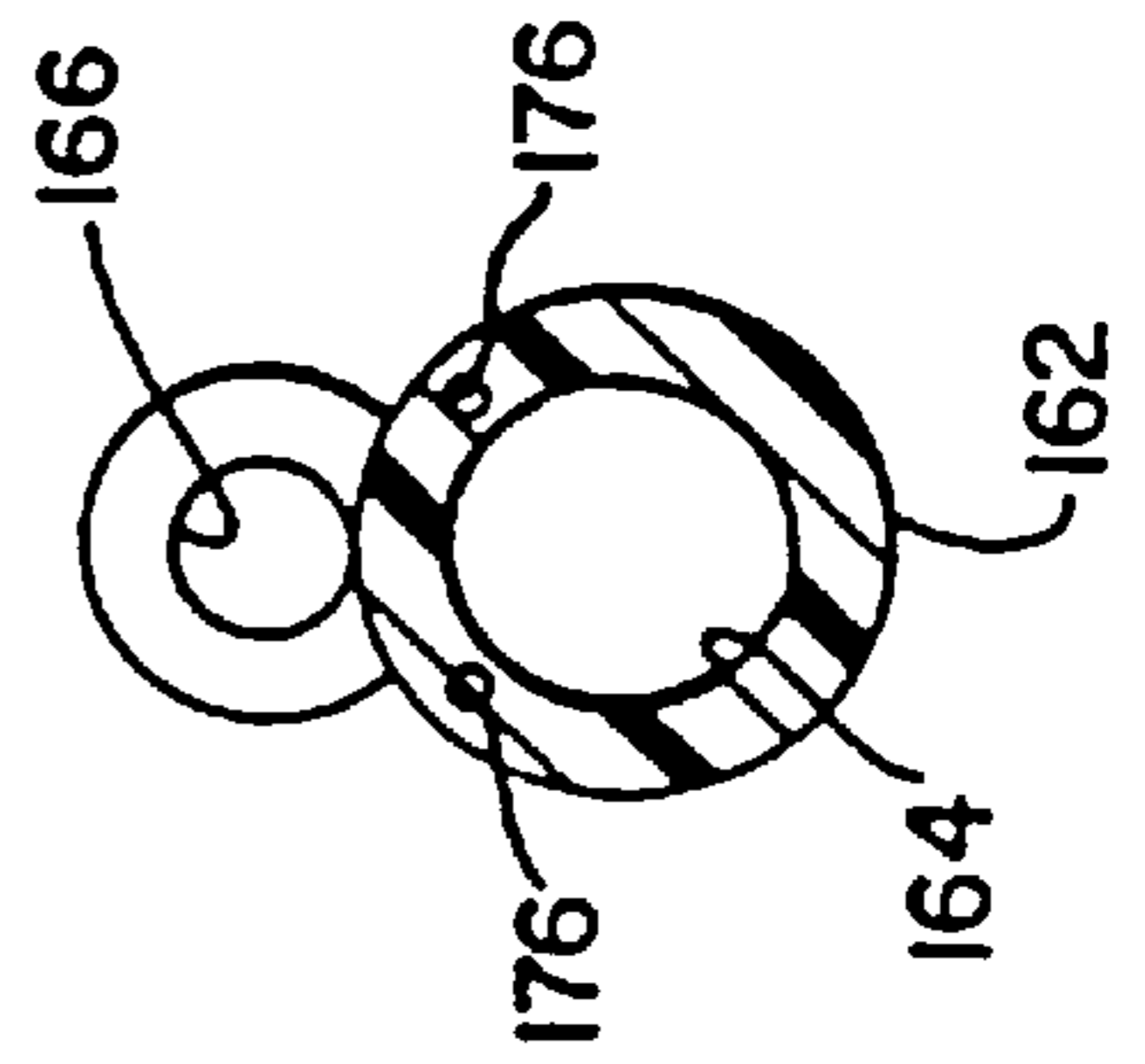


FIG. 19

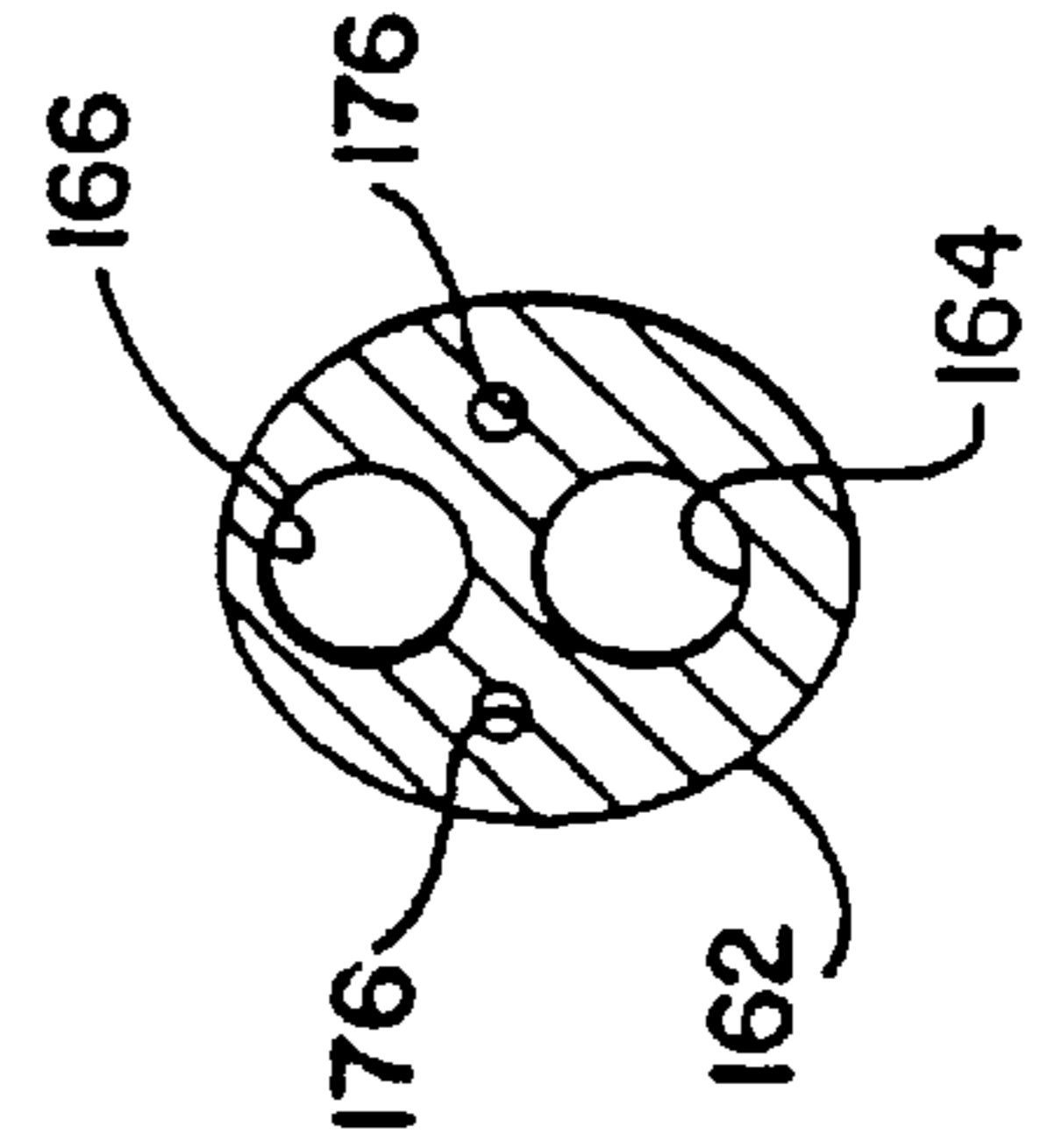
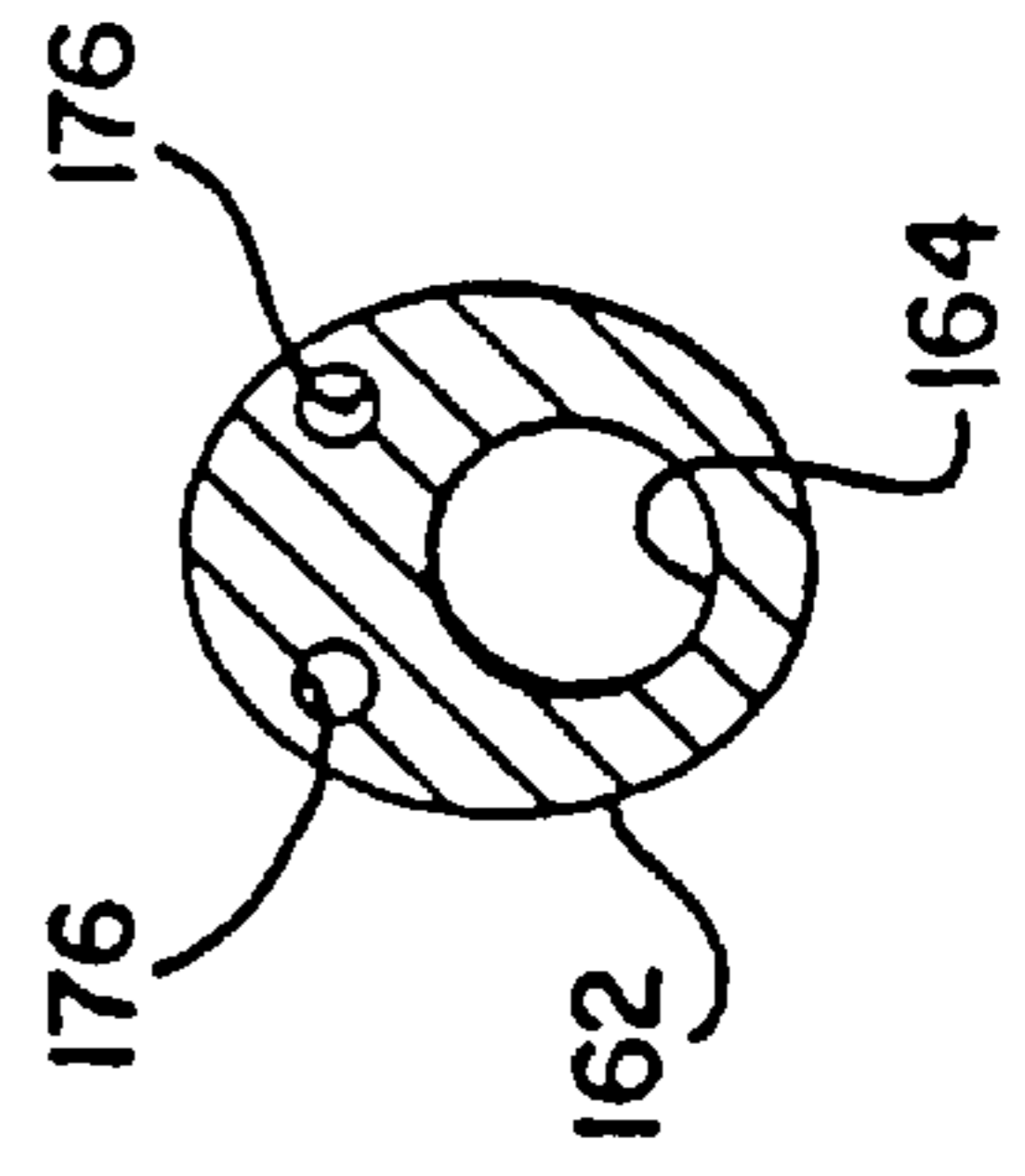


FIG. 20



**INTRAVASCULAR DEVICE SUCH AS
INTRODUCER SHEATH OR BALLOON
CATHETER OR THE LIKE AND METHODS
FOR USE THEREOF**

This application is a continuation of U.S. application Ser. No. 08/075,681, Pending, filed Jun. 11, 1993, which is in turn a continuation of U.S. application Ser. No. 07/809,715, filed Dec. 18, 1991, now U.S. Pat. No. 5,219,335, issued Jun. 15, 1993, which is in turn a continuation-in-part of U.S. application Ser. No. 07/704,828, filed May 23, 1991, now abandoned. This application is also a continuation-in-part of U.S. application Ser. No. 07/946,000, filed Sep. 15, 1992, now abandoned, which is in turn a continuation of U.S. application Ser. No. 07/704,828, filed May 23, 1991, now abandoned. All of the above-identified applications and patents are expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to intravascular devices and, in particular, to an intravascular device such as an improved introducer sheath used for positioning a catheter, imager, or other device in the vascular system of a patient or an intravascular device such as a balloon catheter with a new design and construction.

Various therapies have been developed for treating vascular disease or other conditions that occlude or reduce the lumen size of portions of the vascular system. Such therapeutic techniques include angioplasty, atherectomy, laser irradiation, and so on. Diagnostic techniques have been developed to measure or image the extent of an occlusion of a vessel (e.g., stenosis). Such diagnostic techniques include ultrasonic imaging, Doppler measurements, and so on. These therapies and diagnostic techniques have achieved acceptance because of their effectiveness as well as the fact that they can be performed through a minor surgical procedure that is relatively non-disruptive to the patient.

Therapeutic and diagnostic procedures, such as those described above, rely on the positioning of a device into the vascular system of a patient via an incision at a location remote from the site of the stenosis, such as the femoral artery. Because each of the aforementioned therapies and diagnostic procedures relies upon positioning a device in the afflicted area, an important defining factor limiting the effective deployment of any of these devices is how small the device can be made. It is often in vessels of small inner diameters or tortuous passage ways that stenosis occurs. Thus, it is often preferable to make such therapeutic and diagnostic devices as small as possible to fit into remote coronary sites or other vessel locations where the vessel lumen inner diameters are very small.

Some therapeutic and diagnostic devices include their own guidewires located at the distal ends thereof to facilitate positioning in remote vessel locations. Other devices use an over-the-wire approach in which a central lumen of the device can accommodate a guidewire that is movable in relation to the device to facilitate positioning the device in a remote vessel location. Both of these approaches are very useful and are widely used. However, when such therapeutic or diagnostic devices are adapted with a positioning feature, such as a guidewire tip or a central lumen, the addition of such a positioning feature can increase the size of the device somewhat, thereby establishing a limitation on the size of a vessel into which it can be deployed that is larger than if such an additional feature were omitted.

Introducer sheaths have been employed to facilitate positioning therapeutic and diagnostic devices in remote regions

of the vascular system. An introducer sheath can be a catheter-like device. In a typical prior introducer sheath, the distal end of the introducer sheath is positioned inside of the guide catheter close to the desired site and the therapeutic or diagnostic device is inserted through the lumen of the introducer sheath out the distal end thereof into the vessel location. The introducer sheath also provides the advantage that it can support the therapeutic or diagnostic device over all but the most distal end thereof. Introducer sheaths may be positioned by a guidewire that is first inserted through the lumen of the introducer sheath and then withdrawn to allow placement of the therapeutic or diagnostic device to be installed into the lumen.

A disadvantage of using such a prior introducer sheath is that if it is necessary to reposition the therapeutic or diagnostic device, the introducer sheath may also have to be repositioned. Repositioning of the introducer sheath may require withdrawing the therapeutic or diagnostic device, installing a guidewire into the lumen of the introducer sheath, positioning the guidewire past the distal end of the introducer sheath to the desired location, repositioning the introducer sheath, withdrawing the guidewire, and reintroducing the therapeutic or diagnostic device. This can be a time consuming and tedious process.

Accordingly, it is an object of the present invention to provide an introducer sheath that facilitates use and placement of devices in a vessel of a patient.

It is another object of the present invention to provide an introducer sheath that permits use in remote, distal portions of patient's vasculature.

SUMMARY OF THE INVENTION

According to a first aspect of the invention, there is provided an intravascular device such as an introducer sheath or a balloon catheter, and methods for use thereof, comprising an elongate member having a proximal end and a distal end and a first lumen and a second lumen. The first lumen communicates with a first proximal opening at the proximal end of the elongate member and with a distal opening at the distal end of the elongate member. The second lumen terminates distally and communicates with the first lumen at a location proximal of the first distal opening and has a proximal opening located proximally therefrom. One or more perfusion openings may be located in the device to allow blood flow therethrough. The proximal opening of the second lumen may be located distally of the proximal opening of the first lumen. A balloon may be located on a distal portion of the elongate shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a first embodiment of the present invention.

FIG. 2a shows a cross-section of the embodiment of FIG. 1 along line 2a-2a'.

FIG. 2b shows a cross-section of the embodiment of FIG. 1 along line 2b-2b'.

FIG. 3 shows another embodiment of the present invention.

FIG. 4 shows a cross section of the embodiment of FIG. 3 along line 4-4'.

FIG. 5 shows a cross section corresponding to line of FIG. 4-4' of FIG. 3 of an alternative embodiment

FIG. 6 shows a cross section corresponding to line of FIG. 4-4' of FIG. 3 of an alternative embodiment.

FIG. 7 shows a cross section corresponding to line of FIG. 4-4' of FIG. 3 of an alternative embodiment.

FIG. 8 shows a cross section corresponding to of FIG. 3 of an alternative embodiment.

FIG. 9 shows a longitudinal cross section of another alternative embodiment.

FIG. 10 shows another embodiment of the present invention.

FIG. 11 is a cross section corresponding to line 11–11' of FIG. 10.

FIG. 12 shows another embodiment of the present invention.

FIG. 13 is a cross-section corresponding to line 13–13' of FIG. 12.

FIG. 14 shows another embodiment of the present invention.

FIG. 15 is a cross-section corresponding to line 15–15' of FIG. 14.

FIG. 16 is a cross-section corresponding to line 16–16' of FIG. 14.

FIG. 17 shows another embodiment of the present invention.

FIG. 18 is a cross-section corresponding to line 18–18' of FIG. 17.

FIG. 19 is a cross-section corresponding to line 19–19' of FIG. 17.

FIG. 20 is a cross-section corresponding to line 20–20' of FIG. 17.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

Referring to FIG. 1 there is depicted a first preferred embodiment of the present invention. This embodiment is an introducer sheath 10. The introducer sheath 10 has a proximal end 12 and a distal end 14. In one embodiment, the introducer sheath 10 is approximately 130 cm in length, although other lengths may be used where appropriate. The introducer sheath 10 is used to position devices into the vascular system of a patient.

At the proximal end of the introducer sheath is a manifold 16. The manifold has two ports or openings: a main port 18 and an auxiliary port 20. The main port 18 communicates with a first or main lumen 22 of the introducer sheath, and the auxiliary port 20 communicates with a second or auxiliary lumen 24 of the introducer sheath. The main lumen 22 and the auxiliary lumen 24 are positioned adjacent to each other and extend parallel to each other distally from the proximal end 12 of the introducer sheath. The outside walls of the main and auxiliary lumens are connected together, as shown in FIG. 2a, so as to form an integral elongate catheter-like member. The main and auxiliary lumens may be of the same size or may be of different sizes. In one preferred embodiment, the main lumen 22 has an inside diameter of 0.035 to 0.050 inches, and the auxiliary lumen has an inside diameter of 0.018 to 0.021 inches. The outside dimension of the introducer sheath 10 in this section is approximately 0.065 to 0.086 inches.

The main and auxiliary lumens extend parallel to each other to a junction location 26. The junction location 26 is proximate of the distal end 14 of the introducer sheath. In a preferred embodiment, the junction location 26 is approximately 8 inches from the distal end 14 of the introducer sheath.

At the junction location 26, the auxiliary lumen 24 terminates. At the junction location 26, the main lumen 22 and the auxiliary lumen 24 join together and communicate

with each other. Preferably, the auxiliary lumen 24 merges into the main lumen 22 in an tapering, inclined connection that forms a communicating port 30 between the main and the auxiliary lumens. The main lumen 22 extends distally from the junction location 26, as shown in FIG. 2b. The main lumen 22 terminates in a distal lumen opening 32 at the distal end 14 of the introducer sheath.

One or more markers 33 may be located at or proximate to the distal end 14. These markers may be formed of a radiopaque material such as platinum, gold, tungsten, iridium, alloys thereof. The markers 33 may be imbedded in the material forming the distal portion of the introducer sheath or may be attached by an adhesive or mechanical connection or other means. The markers serve to enable a physician to determine the position of the introducer sheath when it is in the patient's body by well known radioscopic means.

The introducer sheath may be used as follows: The introducer sheath 10 is positioned in the vascular system of a patient in a manner as is known in the art. The distal end 14 of the introducer sheath 10 is positioned close to the location of interest in the vascular system. This location may be an area that the physician may want to image by means of an ultrasonic imaging device. Alternatively, it may be an area where the physician may want to position a balloon device or an atherectomy device for the purpose of reducing or removing a stenosis. The proximal end 12 of the introducer sheath remains positioned outside the patient's body. A guidewire is positioned in the auxiliary lumen 24. The guidewire may be positioned in the auxiliary lumen 24 either before the introducer sheath is inserted into the patient's body or afterward. The guidewire may be used to facilitate positioning of the introducer sheath. To use the guidewire for this purpose, the guidewire is extended through the communicating port 30 from the auxiliary lumen 24 into the main lumen 22 and out the distal lumen opening 32 past the distal end 12. In this position, the guidewire may be used to pass narrow or tortuous vessel regions that could be difficult or impossible for the introducer sheath to traverse by itself. The guidewire may have a formable or steerable tip located on the distal end thereof to facilitate traversing vessel regions. Once the guidewire is positioned as desired, the introducer sheath may be moved distally on the guidewire into its desired position. After the introducer sheath is in the desired position, the guidewire is withdrawn proximally into the auxiliary lumen 24. Because the communicating port 30 between the main and the auxiliary lumens is preferably inclined, withdrawal of the guidewire is facilitated. The therapeutic or imaging device is positioned, or has been positioned, in the main lumen 22 with the distal end of the device proximal of the communicating port 30. After the guidewire is withdrawn into the auxiliary lumen 24, the device can be extended distally past the communicating port 30, past the distal main lumen opening 32, and into the desired vessel region.

This embodiment of the introducer sheath has the advantage that, if repositioning of the introducer sheath is required, such as due to a need to reposition the therapeutic or diagnostic device, the device need not be totally withdrawn. Further, the guidewire can readily be positioned near the distal end of the introducer sheath in the auxiliary lumen. For example, if repositioning of the therapeutic or diagnostic device is required, first the device is withdrawn into the main lumen 22 proximal of the communicating port 30. Then, the guidewire is extended from its position in the auxiliary lumen 2, past the communicating port 30, into the main lumen 22, and out the main distal lumen opening 32 into the

patient's vessel. The guidewire may then be used to facilitate repositioning the introducer sheath. After the introducer sheath has been repositioned as desired, the guidewire is again withdrawn into the auxiliary lumen **24** and the device extended again past the communicating port **30**, past the main lumen distal opening **32**, into the patient's vessel. Thus, with the present embodiment, the guidewire can be readily at hand to facilitate repositioning of the introducer sheath and need not be withdrawn entirely when other devices are used in the introducer sheath.

This embodiment of the introducer sheath provides the advantage that it includes two or more lumens at a proximal end and throughout most of its length to accommodate two or more devices, such as a therapeutic or diagnostic device in one lumen and, in another lumen, a guidewire used to facilitate positioning the device. In portions of the patient's vessel corresponding to this proximal portion of the introducer sheath, the vessel size is likely to be relatively large. Therefore, minimizing the overall exterior size of the introducer sheath is not essential and the vessel can likely readily accommodate the dual lumen proximal portion of the introducer sheath. However, at the distal portion of the introducer sheath, where the exterior dimensions of the introducer sheath are critical and ultimately define the vessel size limit of the device, the introducer sheath has only a single lumen. Thus, with the present embodiment, therapeutic and diagnostic devices can be positioned in distal regions of a patient's vascular system.

Although the above described embodiment of the present invention has been described in terms of using a guidewire in one lumen and a therapeutic or diagnostic device another lumen, the present embodiment should be construed to include other variations and uses. For example, a therapeutic device can occupy one lumen and a diagnostic device can occupy another. The diagnostic device may be an ultrasonic imaging device used to obtain ultrasonic images of the patient's vessel walls. After the images are obtained, the imager may be withdrawn and the therapeutic device, which may be an atherectomy device for example, may be extended from the distal end of the introducer sheath to remove the stenosis. Other combinations of devices are also contemplated within the scope of the invention.

The above described embodiment may also be used with more than two devices. For example, if a guidewire exchange is necessary, perhaps because a different size guidewire is considered necessary, the first guidewire may be totally withdrawn from the auxiliary lumen and a second guidewire inserted. Alternatively, the second guidewire may be installed into the main lumen if it is not otherwise occupied.

The above-described embodiment has been described in terms of an introducer sheath with a main and an auxiliary lumen. In further embodiments, more than two lumens may be provided, consistent with any limitations on the overall exterior dimensions of the introducer sheath.

The introducer sheath may be made of an extruded polymeric material. Polyethylene is the preferred embodiment; however, either polyurethane or PTFE Teflon™ also provide favorable construction. Use of a polyurethane is enhanced by applying a coating to the inner and outer surfaces to enhance lubricity. Alternatively, the introducer sheath may be formed of an acoustically transparent material, such as TPX, so that ultrasound imaging may be performed through the sheath material. Ultrasonic imaging may alternatively be performed by extending an imaging probe out of the distal end of the introducer catheter.

The dual lumen configuration of the introducer sheath may be formed in a single extrusion process. Alternatively, two individual tubes may be joined together by an adhesive joint or a thermal process. A single extrusion, dual-lumen tubing is the preferred embodiment.

In one alternative method of construction, the introducer sheath is made by starting with a dual lumen tubing and removing one of the lumens in a distal portion thereof. This may be done by slicing off one of the lumens by a cutting apparatus. Alternatively, a distal end of the dual lumen tubing may drawn through a heated die to reform the two lumens into one at the distal portion. During this reforming process, the walls may be thinned in the distal portion to make the introducer sheath more flexible in the distal portion.

Referring to FIGS. **3** and **4**, there is shown another embodiment of the present invention. This embodiment includes a positioning member **40**. The positioning member **40** is slidably located in a lumen of an introducer sheath which may be similar or identical to the introducer sheath of the above-described embodiment of the invention. Accordingly, like numerals will be used in reference to the introducer sheath in this embodiment of the invention.

The positioning member **40** is located in the introducer sheath **10** in the lumen thereof that extends to the distal end **14** of the introducer sheath. In this embodiment, this lumen is the main or first lumen **22**. The positioning member **40** includes a holding member **42** sized and adapted to be slidably positioned in the main lumen **22**. The holding member **42** preferably has a cylindrical shape that tapers toward a distal end thereof. The holding member **42** has an outside diameter that is somewhat less than the inner diameter of the main lumen so that it can be readily moved proximally and distally in the main lumen **22** by sliding back and forth. The holding member **42** is tapered toward the distal end **44** to facilitate movement in a distal direction in the main lumen **22**. The holding member **42** itself also includes an inner lumen **46** that extends through the holding member **42**. The inner lumen **46** has a proximal opening **48** and a distal opening **50**.

Connected to a proximal side of the holding member **42** adjacent to the proximal opening **48** of the inner lumen **46** is a proximal positioning wire **52**. The positioning wire **52** forms an elongate rearward extension of the positioning member **40**. The positioning wire **52** may be a wire made of metal or may be another elongate member. The **52** connects to the holding member **42** and extends proximally through the main lumen **22** and out the proximal end of the introducer sheath. The proximal end of the proximal positioning wire **52** may be used to move the holding member **42** proximally and distally so that the positioning member can be slidably positioned in the main lumen **22**. The positioning member **40** can accommodate a device, such as guidewire, through the lumen **46** of the holding member **42**. The guidewire may have very small diameter, such as 0.010 inches, in order to traverse vessel passages of correspondingly small diameter. The positioning member **40** is used to facilitate holding and positioning a device, such as a guidewire, that may have a diameter substantially smaller than the inner diameter of the main lumen **22**. The guidewire is positioned in the lumen **46** of the holding member **42**. This may be done external to the introducer sheath, if desired. Then the holding member **42** with the guidewire installed through it is inserted into the main lumen **22** of the introducer sheath. The holding member **42** with the included guidewire is advanced distally in the main lumen **22** of the introducer sheath by manually advancing the proximal end

of the positioning wire **52**. The holding member **42** may be advanced past the communicating port **30** of the introducer sheath to a location just proximal of the main lumen distal opening **32**. The guidewire may be extended distally from that point by advancing the guidewire distally with respect to the positioning member **40**. This may be accomplished manually from the proximal end as well. By means of the positioning member **40**, a guidewire may be used with the introducer sheath in a lumen thereof. Alternatively, devices other than a guidewire may be positioned by means of the positioning member **40**. Such devices include balloon catheters, atherectomy devices, imagers, and so on.

Referring to FIGS. **5** to **8**, there are shown alternative embodiments of the present invention. These alternative embodiments represent different lumen configurations and geometries for the proximal (dual lumen portion) of the introducer sheath. These alternative embodiments may provide specific manufacturing or operational advantages.

Included in the table below are presently preferred alternative dimensions for the embodiments of FIGS. **5** to **8**.

Config.	Desc.	Dim A	Dim B	Dim C	Dim D	Dim E
1	.014 GW	.004	.004	.018	.035	.065
2	.014 GW	.004	.004	.018	.040	.070
3	.014 GW	.004	.004	.018	.045	.075
4	.014 GW	.004	.004	.018	.050	.080
5	.018 GW	.005	.005	.021	.035	.071
6	.018 GW	.005	.005	.021	.040	.076
7	.018 GW	.005	.005	.021	.045	.081
8	.018 GW	.005	.005	.021	.050	.086

Referring to FIG. **9**, there is depicted another alternative embodiment of the present invention. In this embodiment, there is included a support member **60** located in the distal portion of the introducer sheath. The support member **60** may preferably be formed of a coil of a flat metal wire stock. The support member **60** may be formed of gold, platinum, tungsten, iridium, or alloys thereof to provide for radiopacity, if desired. The support member **60** may alternatively be in the form of a braid or other configuration. The support member **60** may be located on the interior of the sheath in the main lumen **22** at a distal portion thereof to provide for resistance to collapse or to provide for radiopacity. Alternatively, the support member **60** may be located on the exterior of the sheath and bonded or otherwise connected thereto.

Referring to FIGS. **10** and **11**, there is depicted another embodiment of the present invention. In this embodiment, an introducer sheath **70** is provided formed of material(s) and with dimensions similar or identical to the introducer sheath **10**, described above. The introducer sheath **70** has a first or main lumen **72** and a second or auxiliary lumen **74** communicating with ports **76** and **78**, respectively, of a manifold **80**. The auxiliary lumen **74** terminates at and communicates with the main lumen **72** at a location **82** which is proximal of a distal end **84** of the introducer sheath **70** at which the main lumen **72** terminates in a main lumen distal opening **86**.

In this embodiment of the present invention, one or more openings **88** are located in the introducer sheath **10** proximal of the location **82**. The openings **88** allow the introducer sheath **70** to provide for perfusion during use when positioned intravascularly. The openings **88** extend through a portion of the introducer sheath wall so that the interior and the exterior of the introducer sheath **70** may be in fluid

communication. In a preferred embodiment, the one or more holes **88** are located in the portion of the introducer sheath **70** corresponding to the wall of the auxiliary lumen **74** so that the auxiliary lumen interior is in fluid communication with the exterior of the introducer sheath **70**. Alternatively, the one or more openings **88** may be located in a portion of the introducer sheath corresponding to the main lumen **72** or in portions of the introducer sheath corresponding to both the main and auxiliary lumens. The one or more openings **88** may include 6 openings or, alternatively, more or less than 6 openings may be provided. Each opening may be approximately 0.010 inches in diameter and extend through the introducer sheath wall either perpendicularly or at an angle to a normal axial direction. If more than one opening is provided, the openings may be spaced from each other by approximately 0.25 inches or may be spaced from each other by other distances either regularly or irregularly. Also, the opening **88** may be aligned along the introducer sheath in a straight line or may be provided in a staggered or other arrangement. In one embodiment, the openings **88** are located in the auxiliary lumen wall beginning at a location approximately $\frac{1}{2}$ inch proximally from the communication location **82** and extending proximally therefrom.

An exemplary method for using the introducer sheath **70** is described as follows: The introducer sheath **70** may be used in conjunction with an angioplasty procedure in which a balloon dilation catheter is positioned across a region of a person's vascular system narrowed by atherosclerotic disease, e.g., a stenosis. The location at which the vessel narrowing occurs may be determined by angiographic methods known in the art, or by other methods such as ultrasound, optical fiber, etc. According to this embodiment, the introducer sheath **70** is positioned in the vascular system of the patient in a manner like the embodiments described above. A guidewire (not shown) is installed into the vascular system via the auxiliary lumen **74**. A balloon dilation catheter of the fixed wire type is installed in the main lumen **72** so that a distal end of the dilation catheter is proximal of the location **82**. The balloon catheter may be an ACE catheter manufactured by SciMed Life Systems, Inc. of Maple Grove, Minn. The introducer sheath **70** is advanced so that the distal end **84** of the introducer sheath is proximal of the site of the stenosis. The guidewire is extended out the distal end of the introducer sheath **70** and an attempt is made to cross the diseased region. If successful, the introducer sheath **70** is advanced distally over the guidewire so that the distal end is across the stenosis. Then, the guidewire is withdrawn proximally so that a proximal end is proximal of the location **82**. Then, the dilation catheter is advanced so that the balloon is across the stenosis and the introducer sheath is withdrawn slightly so that the balloon portion of the dilation catheter is at the narrowed site. Dilation is attempted according to known techniques. If it is determined that a different dilation catheter is needed, e.g., with a different size balloon for example, the introducer sheath is advanced over the first dilation catheter and across the stenosis. Then, the first dilation catheter is withdrawn. The guidewire is moved proximally several inches in the auxiliary lumen **74** so that at least some of the openings **88** are distal of the distal end of the guidewire. Blood can then perfuse through the introducer sheath **70** via the openings **88**, the distal portion of the auxiliary lumen **74**, the distal portion of the main lumen **72**, and the distal opening **86** of the main lumen **72**. This allows blood to perfuse across the stenosis while a second dilation catheter is prepped and installed into the main lumen **72**. Then, the second dilation catheter is advanced through the main lumen **72** and out the distal end **84** of the introducer

sheath **70** so that the balloon of the second dilation catheter is positioned across the stenosis. Dilation is then attempted with the second balloon catheter.

It can readily be appreciated that there are various alternative methods of use. For example, instead of exchanging a first dilation balloon catheter for another dilation balloon catheter, it may be indicated after a balloon angioplasty that an atherectomy device is needed, e.g., to treat or remove loose tissue. The introducer sheath **70** can be installed across the site to allow blood perfusion while the atherectomy device is prepared and installed. An advantage of the present embodiment is that not only can a secure path for blood perfusion be maintained across a vessel site, but also multiple paths for guidewires, balloon catheter, atherectomy devices, imaging devices, etc., can also be maintained across the site.

Referring to FIGS. **12** and **13**, there is depicted another embodiment of the present invention. In this embodiment, an introducer sheath **100** is provided formed of material(s) and with dimensions similar or identical to introducer sheaths **10** and **70**, described above. The introducer sheath **100** has a first or main lumen **102** and a second or auxiliary lumen **104**. The first lumen **102** communicates proximally with a port **106** of a manifold **110**. The main lumen **102** terminates distally in a main lumen distal opening **112**. An auxiliary lumen **104** terminates distally at and communicates with the main lumen **102** at a location **114** which is proximal of a distal end **116** of the introducer sheath **100**.

In this embodiment **100**, the auxiliary lumen **104** extends proximally from the location **114** and terminates at an opening **117** at a location **118** distal of a proximal end **120** of the introducer sheath **100**. (In addition, in this embodiment **100** of the introducer sheath, one or more openings **119** may be provided in a portion of the wall of the introducer sheath **100** proximal of the location **114** to provide for perfusion as in the embodiment depicted in FIGS. **10** and **11**). The length of the auxiliary lumen **104**, i.e., the distance between the locations **114** and **118**, may be any length, but in one embodiment, the length is approximately 4 inches.

This embodiment of the introducer sheath **100** allows for quick exchange of one introducer sheath for another. Because the auxiliary lumen **104** terminates at a location near the distal end **116** of the introducer sheath **100**, the introducer sheath **100** can be exchanged for another intravascular device, such as another balloon catheter, or even another introducer sheath perhaps of a different size, over a positioning guidewire extending through the auxiliary lumen **104** and out the end **116** of the sheath while leaving the guidewire in place in the vessel with a distal end across the site.

An exemplary method for using the introducer sheath **100** is described as follows: The introducer sheath **100** may be used in conjunction with an angioplasty procedure in which a balloon dilation catheter is positioned across a region of a person's vascular system narrowed by arteriosclerotic disease, e.g., a stenosis. The location at which the vessel narrowing occurs may be determined by angiographic methods known in the art, or by other methods such as ultrasound, optical fiber, etc. According to this embodiment, a first guidewire (not shown) is installed in the main lumen **102** and a second guidewire is installed into the auxiliary lumen **104**. The first guidewire may be a conventional guidewire used for positioning and the second guidewire may be an imaging guidewire that is used scan the vasculature with ultrasound to produce images of the vessel geometry. (An imaging guidewire of the type considered

herein is disclosed in copending application Ser. No. 07/668, 919, filed Mar. 13, 1991, the disclosure of which is incorporated herein by reference.) The introducer sheath **100** is positioned in the vascular system of the patient in a manner like the embodiments described above. An attempt is made to cross the lesion with the first guidewire. If successful, the introducer sheath may be advanced over the lesion, the first guidewire withdrawn entirely into the auxiliary lumen **104** and the imaging guidewire advanced to obtain images of the vessel geometry. However, it may occur that the introducer sheath **100** is too large to cross the lesion and therefore an introducer sheath of a different size is required. With the present embodiment, a first introducer sheath can be readily exchanged for another introducer sheath without withdrawing the first guidewire from its position across the lesion. In such a circumstance, the first guidewire is left in place across the lesion and the introducer sheath **100** is withdrawn thereover. Then, another introducer sheath having different dimensions is advanced over the same first positioning guidewire and another attempt is made to cross the stenosis.

(If it becomes necessary to exchange a guidewire in the auxiliary lumen **104** of the embodiment of FIGS. **12** and **13**, this can be accomplished by means of a guidewire sheath as disclosed in copending application Ser. No. 07/725,064 filed Jul. 5, 1991, the disclosure of which is incorporated herein by reference).

Referring to FIGS. **14–16**, there is depicted another embodiment of the present invention. In this embodiment, a multi-guidewire lumen design is incorporated into a balloon catheter **140**. The balloon catheter **140** may be formed of material(s) and with dimensions similar or identical to commercially available balloon catheters such as the Skinny or MVP manufactured by SciMed Life Systems, Inc. of Maple Grove, Minn., except that instead of a single guidewire lumen extending through the shaft and balloon, the balloon catheter **140** includes an elongate shaft **142** having a first or main lumen **144** and a second or auxiliary lumen **146** communicating with ports of a proximally located manifold (not shown). The auxiliary lumen **146** terminates at and communicates with the main lumen **144** at a location **148** which is proximal of a distal end **150** of the balloon catheter **140**. The main lumen **144** terminates in a main lumen distal opening **152** at the distal end **150**. In this embodiment, an inflatable balloon **154** is located on a distal portion of the elongate shaft **142**. One or more inflation lumens **156** extend through the elongate shaft **142** and communicate with the interior of the balloon **184**. Inflation fluid is conveyed by the path formed by the one or more inflation lumens **154** to inflate and deflate the balloon **154** in a manner that is known in the art for the purposes of dilating narrowed vessels of the body.

This multi-lumen dilation balloon catheter **140** of this embodiment may be provided, in alternative embodiments, with features of the other embodiments, such as perfusion openings **158** located in a portion of the elongate member **142** proximal of the balloon **154** or proximal of the location **148** at which the main and the auxiliary lumens communicate.

A method for using the present embodiment **140** is as follows: A first guidewire is positioned in the main lumen **144** and a second guidewire is positioned in the auxiliary lumen **146**. The first wire may be of a conventional type used for positioning over-the-wire and single-operator-exchange type catheters. The second guidewire may be of an imaging type, as disclosed in copending application Ser. No. 07/104, 828, filed May 23, 1991, the disclosure of which is incorporated herein by reference. The imaging guidewire

includes an ultrasonic transducer located at the distal portion adapted to scan the vasculature to obtain images thereof. The balloon catheter **140** is positioned in the vascular system of a patient in a manner that is known in the art. This may typically involve an incision into the body of the patient in the groin to provide access to the femoral artery. Typically, a short introducer sheath (not to be confused with the long multi-lumen introducer sheath described elsewhere in this specification) is positioned in the artery and a guide catheter installed therein to provide access to the ostium. The balloon catheter **140** and the first and second guidewires are advanced to the coronary site at which treatment is to take place. The first guidewire is used to position the balloon catheter and may possess characteristics that allow it to cross tortuous portions of the vasculature. Once the first guidewire is positioned across the lesion or stenosis, the balloon catheter **140** may be advanced over it in a usual manner so that the balloon portion **154** is at the vessel treatment site. Then, the first guidewire is withdrawn proximal of the location **148** and the imaging guidewire is advanced so that it can scan the vasculature through the catheter **140**. (In order to do this, the catheter **140** can be provided so that at least a portion thereof is formed of a material that is ultrasonically transparent, such as TPX.) This imaging can be useful to the physician to diagnose the extent of the lesion. The imaging may be used in conjunction with other diagnostic techniques such as angiographic dyes. If the physician is satisfied with the information obtained, the dilation may take place in the usual manner. Then, after deflation, ultrasonic images may be obtained again to observe the efficiency of treatment. Additional dilations or other therapy may be indicated if the physician is not satisfied with the results observed. Such additional therapies may be initiated while a path across the vessel narrowing site is available thereby facilitating such additional procedures.

It can readily be appreciated that there are numerous alternative methods taking advantage of the multiple guidewire lumens of this embodiment. For example, both the first and the second guidewires can be for positioning but with different characteristics. For instance, one guidewire can be relatively flexible and the other can be relatively stiff. If the physician considers that both may be needed, possibly alternatively, both the guidewires can be ready and in the balloon catheter ready for use. The guidewire can be alternatively retracted and extended as needed.

Referring to FIGS. **17–20**, there is depicted another embodiment of the present invention. In this embodiment, a multi-guidewire lumen design is incorporated into a balloon catheter **160**. As in the previously-described embodiments, the balloon catheter **160** may be formed of material(s) and with dimensions similar or identical to commercially available balloon catheters. The balloon catheter **160** differs from the balloon catheter **140** shown in FIGS. **14–16** in that one of the wire lumens terminates at a location distal of the proximal end of the catheter. The balloon catheter **160** includes an elongate shaft **162** having a first or main lumen **164** and a second or auxiliary lumen **166**. The main lumen **164** communicates with a port of a proximally located manifold (not shown). The auxiliary lumen **166** terminates distally at and communicates with the main lumen **164** at a location **168** which is proximal of a distal end **170** of the balloon catheter **160**. The main lumen **164** terminates in a main lumen distal opening **172** at the distal end **170**. An inflatable balloon **174** is located on a distal portion of the elongate shaft **162**. One or more inflation lumens **176** extend through the elongate shaft and communicate with the interior of the balloon **174**. Inflation fluid is conveyed by the

path formed by the one or more inflation lumens **176**. This multi-lumen inflation balloon of the present embodiment may be provided with perfusion openings **178** located in a portion of the elongate member proximal of the balloon or proximal of the location at which the main and the auxiliary lumen communicate. In this embodiment, the auxiliary lumen **66** terminates at a location **180** so that the auxiliary lumen **166** is relatively short, e.g., 4–6 inches.

The relatively short auxiliary lumen **166** enables a physician to facilitate a quick exchange of this balloon catheter with another, for example, if a balloon of different dimensions is required. Such an exchange can be performed in a manner as is done now with balloon catheters such as described above with respect to the embodiment shown in FIGS. **12** and **13**. Accordingly, an exemplary method of operating the balloon catheter **160** would be as follows: A guidewire is positioned in the auxiliary lumen **166** and the guidewire and the balloon catheter **160** are advanced through a guide catheter intravascularly. An attempt is made to cross the stenosis with the guidewire. If the guidewire can be successfully positioned across the stenosis, the catheter **160** is advanced over the guidewire and across the stenosis. Then, the guidewire is withdrawn so that the distal end of the guidewire is proximal of the location **168**. Then, an imaging guidewire is advanced through the main lumen **164**. The imaging guidewire is advanced out the distal opening **172**. Then, the catheter is withdrawn slightly so that the imaging guidewire can make ultrasonic scans of the vasculature at the site of the stenosis. (Alternatively, the imaging guidewire can scan through the catheter **160** if at least a portion of the catheter, e.g., a window, is formed of an ultrasonically transparent material). Then, the catheter **160** is advanced over the imaging guidewire and the balloon **174** is inflated to dilate the vessel at the site. If a catheter of a different size or a catheter of a different type, e.g., an atherectomy device, is indicated, the balloon catheter **160** can be exchanged for the other catheter device by first withdrawing the imaging guidewire proximally of the location **168**, advancing the positioning guidewire out the distal end **170** and across the stenosis, and exchanging the catheter **160** for the other device over the first (positioning) guidewire.

It is intended that the foregoing detailed description be regarded as illustrative rather than limiting and that it is understood that the following claims including all equivalents are intended to define the scope of the invention.

What is claimed is:

1. A method for sequentially imaging and dilating a region of a subject:

using an ultrasound probe, a guidewire, and a catheter, wherein the catheter comprises an elongate, flexible member having a lumen in its distal length; a dilation balloon attached to the distal length, the outside of the distal length and the balloon being sized for passage into the region of the subject and the lumen having a diameter sized to accept either the guidewire or the ultrasound probe, wherein the lumen splits into a dual lumen proximal of said balloon, the dual lumen comprising a guidewire lumen sized to accept the guidewire and a probe lumen sized to accept the ultrasound probe, the flexible member further comprising a third lumen wherein the third lumen communicates with the balloon, the method comprising the steps of:

advancing the guidewire through the subject until a distal tip of the guidewire is distal of the region of the subject to be imaged;

advancing the catheter along the guidewire until the distal portion has passed into the region to be imaged;

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pulling the guidewire proximally while holding the catheter relatively stationary in the distal and proximal directions within the subject, and leaving the distal tip of the guidewire within the wire lumen;
 advancing the ultrasound probe tip into the distal lumen portion of the catheter;
 preventing the ultrasound probe from extending distally beyond the catheter;
 activating the probe to obtain pre-dilation ultrasound images of the region;
 retracting the probe into the probe lumen;
 advancing the guidewire distally of the catheter tip;
 moving the catheter distally until the balloon passes into said region of the subject; and
 inflating and then deflating the balloon.

2. The method of claim 1, further comprising post-dilation imaging steps of:

repeating the steps for replacing the guidewire with the probe in the distal length of catheter and obtaining post-dilation ultrasound images.

3. The method of claim 1, wherein the step of imaging is performed by fitting ultrasound signals through the balloon.

4. A method for sequentially dilating and then imaging a region of a subject:

using an ultrasound probe, a guidewire, and a catheter, wherein the catheter comprises an elongate flexible member having a lumen in its distal length, a dilation balloon attached to the distal length, the outside of the distal length and balloon being sized for passage into the region of the subject and the lumen having a diameter sized to accept either the guidewire or the ultrasound probe, wherein the lumen splits into a dual lumen proximal of said balloon, the dual lumen comprising a guidewire lumen sized to accept the guidewire and a probe lumen sized to accept the ultrasound probe, the flexible member further comprising a third lumen wherein the third lumen communicates with the balloon, the method comprising the steps of:

advancing the guidewire through the subject until a distal tip of the guidewire is distal of the region of the subject to be imaged;

advancing the catheter through the distal lumen and the guidewire lumen, until the balloon has passed into the region to be dilated;

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inflating and then deflating the balloon by flowing a fluid through the third lumen;

pulling the guidewire proximally, and leaving the distal tip of the guidewire within the wire lumen;

advancing the ultrasound probe tip into the distal lumen portion of the catheter;

preventing the ultrasound probe from extending distally beyond the catheter; and

activating the probe to obtain post-dilation ultrasound images of the region.

5. The method of claim 4, further comprising the steps of: moving the catheter proximally prior to imaging so that the balloon is located proximal to the region of the subject.

6. A method of imaging and dilating a region of a lumen in a subject comprising the steps of:

positioning a guidewire so that the distal tip of the guidewire is within the lumen and distal of a region of the lumen to be imaged and dilated;

advancing a catheter using the guidewire as a guidance device until a distal end of the catheter is within the lumen, and distal of the region of the lumen to be imaged and dilated;

retracting the guidewire until it becomes proximal of the region of the lumen to be imaged and dilated;

advancing an ultrasound probe within the catheter until the tip is within the region of the lumen to be imaged and dilated;

preventing the ultrasound probe from extending distally beyond the catheter;

activating the probe to obtain images;

advancing the catheter using a method comprising the steps of: retracting the probe, advancing the guidewire, and moving the catheter distally using the guidewire as a guidance device until a balloon dilation portion of the catheter is within the region to be imaged and dilated; and

dilating the region of the lumen in the subject by temporarily inflating the balloon through a catheter lumen.

7. The method of claim 6, wherein the imaging is performed through the balloon the steps of moving the catheter between imaging and dilation are omitted.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,022,319
DATED : February 8, 2000
INVENTOR(S) : Lloyd Willard et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 2,

Lines 62, 64 and 66, please delete the first reference to "or FIG."

Column 4,

Line 37, please change "distal end 12" to -- distal end 14 --.

Line 66, please change "lumen 2" to -- lumen 24 --.

Column 6,

Line 36, please change "distal end 44" to -- distal end 14 --.

Column 7,

Line 56, please change "manifold 80" to -- manifold 8 --.

Line 62, please change "sheath 10" to -- sheath 70 --.

Column 10,

Line 47, please change "balloon 184" to -- balloon 154 --.

Line 49, please change "lumens 154" to -- lumens 156 --.

Column 12,

Line 7, please change "lumen 66" to -- lumen 166 --.

Line 7, please change "location 180" to -- location 168 --.

Signed and Sealed this

Thirteenth Day of August, 2002

Attest:



Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office